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EXAMINER	
FRISTOE JR, JOHN K	

ART UNIT	PAPER NUMBER
3754	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/606,262	BECK ET AL.
Examiner	Art Unit	
John K. Fristoe Jr.	3754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 June 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-35 and 91-110 is/are pending in the application.
4a) Of the above claim(s) 12-15, 91 and 97-103 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-6, 9-11, 22-35, 92-96 and 104-110 is/are rejected.

7) Claim(s) 7, 8 and 16-21 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 25 June 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, 16-35, 92-96, and 104-110, drawn to a feeding set adapter and a method of forming the feeding set adapter, classified in class 604, subclass 67.
 - II. Claims 12-15, 91, and 97-103, drawn to a solution delivery system, classified in class 250, subclass 573.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require a first connector, a second connector, or an anti-freeflow mechanism. The subcombination has separate utility such as pumping oil.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Randall Bateman on 8/17/2004 a provisional election was made without traverse to prosecute the invention of I, claims 1-11, 16-35, 92-96, and 104-110. Affirmation of this election must be made by applicant in replying to this Office

action. Claims 12-15, 91, and 97-103 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

6. The current Application was filed as a divisional Application of Application No. 09/836,851. However, since the claimed invention in the prior Application is identical to the current Application's claimed invention, the current Application should have been filed as a continuation. Appropriate correction is required.

Drawings

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "anti-freeflow mechanism being attached to the second connector and disposed in the central pump engaging portion" of claim 7 and "wherein the conduit has a cross section which is diamond shaped" of claim 27, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

8. Claims 1 and 5 are objected to because of the following informalities: "an infusion set" in claim 1, line 5 should be replaced with "said infusion set" since it is previously recited within the claim. "An inflow line" in claim 1, line 6 should be replaced with "said inflow line" since it is previously recited within the claim. "An outflow line" in claim 1, line 6 should be replaced with "said outflow line" since it is previously recited within the claim. "A central pump engaging portion" in claim 5, line 2, should be replaced with "said central engaging portion" since it was previously recited. Appropriate correction is required.

Double Patenting

9. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

10. Claims 92- 94 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 106-108 respectively, of prior U.S. Patent No. 6,659,976. This is a double patenting rejection.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8, 9, 9, and 9, respectively, of U.S. Patent No. 6,659,976 in view of U.S. Pat. No. 5,720,721 (Dumas et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 8, 9, 9, and 9 of U.S. Pat. No. 6,659,976 in view of U.S. Pat. No. 5,720,721 (Dumas et al.) "anticipate" Application claims 1-4, respectively. Accordingly, Application claims 1-4 are not patentably distinct from Patent claims 8, 9, 9, and 9, respectively.

Here Patent claim 8 requires:

A feeding set adapter comprising:

- A first connector configured for attachment to an inflow line of an infusion set and a central pump engaging portion of an infusion set;
- A second connector configured for attachment to an outflow line of an infusion set; and
- An anti-freeflow mechanism disposed in communication with the one of the first connector and the second connector, wherein the anti-freeflow mechanism is configured for disposition in the tubing of the infusion set.

While Application claim 1 requires:

A feeding set adapter comprising:

- A first connector configured for attachment to an inflow line of an infusion set and a central pump engaging portion of an infusion set;
- A second connector configured for attachment to an outflow line of an infusion set;
- An infusion set comprising tubing configured for carrying a fluid and being attached to the first connector and the second connector, the tubing forming at least an inflow line and an outflow line; and
- An anti-freeflow mechanism disposed in communication with the one of the first connector and the second connector, the anti-freeflow mechanism being disposed inside the tubing.

Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since Application claims 1-4 are anticipated by claims 8, 9, 9, and 9, respectively, of U.S. Pat. No. 6,659,976, and since

anticipation is the epitome of obviousness, then Application claims 1-4 are obvious over claims 8, 9, 9, and 9, respectively, of U.S. Pat No. No. 6,659,976.

In addition Application claim 1 requires the tubing forming at least the inflow line and the outflow line, claim 1 of U.S. Pat. No. 6,659,976 only requires that there be an inflow line and an outflow line. Dumas et al. teach a feeding set adapter comprising an inflow line (14), an outflow line (10), and a tube (38) that extends in between. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the feeding set adapter having an inflow line and outflow line of Application claim 1 by adding a tubing in between the inflow line and the outflow line as taught by Dumas et al. since the inflow line and the outflow line must be connecting by a tubing to render the pump operable.

Similarly, claims 2-4 are rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 9, 9, and 9, respectively, for the same reason set forth above.

13. Claims 22-35 and 95 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27-40, and 27, respectively, of U.S. Patent No. 6,659,976. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 27-40 and 27 of U.S. Pat. No. 6,659,976 “anticipate” Application claims 22-35 and 95), respectively. Accordingly, Application claims 22-35 and 95 are not patentably distinct from Patent claims 27-40, and 27, respectively.

Here Patent claim 27 requires:

A feeding set adapter comprising:

- A first connector configured for attachment to an inflow line of an infusion set and a central pump engaging portion of an infusion set;
- A second connector configured for attachment to an outflow line of an infusion set;
- An anti-freeflow mechanism, disposed in communication with the one of the first connector and the second connector; and
- Further comprising a sample cell formed as part of the adapter.

While Application claim 22 requires:

A feeding set adapter comprising:

- A first connector configured for attaching two line of a feeding set;
- An anti-freeflow mechanism disposed in communication with the first connector; and
- A sample cell formed as part of the first connector.

Thus, it is apparent that the more specific Patent claim 27 encompasses Application claim 22.

Following that rationale in *In re Goodman* cited in the preceding paragraph, where Applicant has once been granted a patent containing a claim for the specific or narrower invention, Applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer. Note that since application claim 22 is anticipated by Patent claim 27 and since anticipation is the epitome of obviousness, then Application claim 22 is obvious over Patent claim 27.

Similarly, claims 23-35 and 95 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-40, and 27, respectively, for the same reason set for the above.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claim 106 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is not clear to the examiner how the quantity of light that passes through the sample cell would not be refracted and this is not described within the specification.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 1-3, 5, 6, 9, 92, 107, and 108 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,494,864 (Kerwin et al.). Kerwin et al. disclose a feeding set adapter and a method of preventing freeflow in an infusion set comprising a first connector (42), an inflow line (the portion of the tubing that is pointed to by numeral 12 in figure 1), a central pump engaging portion (located beneath pump 48), a second connector (45), an outflow line (portion of tube leaving element 45 in figure 1), an infusion set, a tubing (12), an anti-freeflow

mechanism (16) disposed in the tubing (figure 1) and it is spaced apart from the first or second connector (figure 1), and wherein the anti-freeflow mechanism comprises a generally ball shaped member (28).

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claim 110 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 5,810,323 (Winterer et al.). Winterer et al. disclose a method for forming an infusion set comprising selecting an infusion set having a tube (col. 2, lines (63-65) having an inflow line (not shown) and an outflow line (not shown), and connecting the inflow line to a first connector and the outflow line to a second connector wherein at least one of the first connector and the second connector has an abutment member (the portion around element 314 in figure 6) attached thereto for limiting radial expansion of the infusion set.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,494,864 (Kerwin et al.) in view of U.S. Pat. No. 5,720,721 (Dumas et al.). Kerwin et al. disclose the above described feeding set adapter but lacks a device for monitoring the pressure

optically. Dumas et al. discloses a device (40) that detects the amount of pressure within a tube (10) and an abutment member (20)) that would minimize the movement of the monitoring device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the feeding set adapter of Kerwin et al. by adding a pressure monitoring device as taught by Dumas et al. in order to prevent a build up or pressure within the tube that may cause a failure of the device.

22. Claims 22-26, 28-35, 93, 94, 96, 104, 105, and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,720,721 (Dumas et al.) in view of U.S. Pat. No. 5,672,887 (Shaw et al.). Dumas et al. disclose a feeding set adapter and a method of forming a feeding set adapter comprising a first connector (the lower 18 in figure 1), an anti-freeflow mechanism (50), and an air detector (40) but lacks a sample cell. Shaw et al. teach a sample cell for an infusion set comprising the sample cell being a part of the first connector (figure 1), the sample cell has a pair of side walls disposed at an angle of 60 degrees (col. 4, lines 3-6), wherein the sample cell has a cross section that is an equilateral triangle (fig. 2) that extends downwardly and inwardly, a housing (20), an air chamber (fig. 2), wherein there are a pair of sidewalls that extend between 45 degrees and 100 degrees (fig. 7E), wherein the housing has base disposed at an angle of about 50 to 60 degrees from each of the sidewalls (fig. 2), an optical sensor and an optical signal emitter (col. 4, lines 27-30), wherein the sample cell is formed integrally with the first connector (fig. 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the feeding set adapter having an air detector of Dumas et al. by having a sample cell with a triangular cross section as taught by Shaw et al. in order to reduce the cost of the medical device.

23. Claim 95 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,720,721 (Dumas et al.) in view of U.S. Pat. No. 5,672,887 (Shaw et al.) as applied to claim 22 above, and further in view of U.S. Pat. No. 6,494,864 (Kerwin et al.). Dumas et al. modified above, discloses a feeding set adapter having a sample cell to detect air within the tube and an anti-freeflow mechanism but lacks an anti-freeflow mechanism disposed within the tube. Kerwin et al. teach a feeding set adapter having an anti-freeflow mechanism disposed within the fluid line. It would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the feeding set adapter having an anti-freeflow mechanism of Dumas et al. by disposing the anti-freeflow mechanism within the tube as taught by Kerwin et al. so that the tube is less likely to break due to excessive pinching of the tube.

Allowable Subject Matter

24. Claims 8 and 16-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John K. Fristoe Jr. whose telephone number is (703) 308-1437. The examiner can normally be reached on Monday-Friday, 7: 00 a.m-4: 30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Louis G. Mancene can be reached on (703) 308-2696. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John K. Fristoe Jr.
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